FOR ARGUMENT

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In the Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,
v.
LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit

**Brief for Amicus Curiae,
Plaintiffs' Legal Committee in MDL Docket No. 1014,
in Support of Cross-Petitioners,
Lora Lohr and Michael Lohr**

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I. INTEREST OF AMICUS CURIAE

Amicus Curiae is the Plaintiffs' Legal Committee appointed by United States District Court Judge Louis C. Bechtle to coordinate litigation on plaintiffs' behalf in *In Re Orthopedic Bone Screw Products Liability Litigation*, MDL Docket No. 1014.

The cases involved in the *Orthopedic Bone Screw Products Liability Litigation* are actions in which plaintiffs suffered

injury as a result of the use of certain "fixation constructs" during spinal surgery and in which the manufacturers' liability is claimed to arise, in part, from conduct which is asserted to be in violation of numerous provisions of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

Approximately 3,000 such cases have been transferred by the Judicial Panel for Multidistrict Litigation to Judge Bechtle of the United States District Court for the Eastern District of Pennsylvania for coordinated and/or consolidated pretrial proceedings pursuant to 28 *U.S.C.* §1407.

In the *Orthopedic Bone Screw Products Liability Litigation*, the defendants have taken the position that the Medical Device Amendments to the Food, Drug and Cosmetic Act preempt some or all of the plaintiffs' claims for relief because the products which caused plaintiffs' injuries are medical devices.

The Court's decision in the instant matter concerning the nature and extent of federal preemption of tort/product liability claims against the manufacturers of medical devices may have an impact on the ultimate disposition of the preemption issue in the *Orthopedic Bone Screw Products Liability Litigation*. Accordingly, the Amicus Curiae has an obvious interest in the resolution of that issue before this Court.

II. SUMMARY OF THE ARGUMENT

The Medical Device Amendments to the Food, Drug and Cosmetic Act limit preemption to state law requirements "with respect to a device intended for human use." Accordingly, the statute preempts only state law requirements that are specifically targeted at medical devices as distinguished from legal requirements of general applicability such as state tort law and products liability principles. This interpretation is one which is required: (1) by the plain meaning of the statute; (2) by the presumptions against preemption; (3) by the principle that obliges courts to defer to regulatory interpretations of a statute; (4) by consideration of the text and structure of the Medical Device Amendments; (5) by the principle of statutory

construction which requires that all the language of a legislative enactment be given effect; and (6) by the principle of statutory construction which examines legislative history to ascertain whether and to what extent Congress intended to preempt state law.

Moreover, by limiting preemption to establishment or enforcement of state "requirements" which are "different from or in addition to" federal requirements established pursuant to the Medical Device Amendments, it is clear that Congress did not intend to preempt state law damage claims which arise from conduct in violation of federal requirements imposed under the Medical Device Amendments. This construction is supported by the plain meaning of the statute, by the principle of statutory construction that requires that all the language of a legislative enactment be given effect and by the principle that requires deference to an agency's interpretation of a statute which it is entrusted to enforce.

III. ARGUMENT

A. General Principles of Federal Preemption Analysis

Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *U.S. Constitution*, Art. VI, cl. 2. Thus, since the Court's decision in *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 403, 427 (1819), the Supreme Court has held that Congress can displace state law.

The question of federal preemption, however, implicates serious principles of federalism which require that "unintended encroachment on the authority of the States" be avoided. *CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 113 S. Ct. 1732, 1737 (1993). Therefore, preemption analysis must begin "with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Accordingly, the Courts "will interpret a statute to pre-empt the traditional state powers only if that result is 'the

clear and manifest purpose of Congress.'" *Department of Revenue of Oregon v. ACF Industries, Inc.*, _____ U.S. _____, 114 S. Ct. 843, 851 (1994), quoting *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). *Accord, e.g., Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) ("The purpose of Congress is the ultimate touchstone" of preemption analysis); *Retail Clerks International Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963) ("The purpose of Congress is the ultimate touchstone.").

Congressional intent to preempt state law may be implied either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively or when state law is in actual conflict with federal law. *Engiish v. General Electric Co.*, 496 U.S. 72, 78-79 (1990). Implied actual conflict preemption occurs where it is "impossible for a private party to comply with both state and federal requirements" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Freightliner Corp. v. Myrick*, _____ U.S. _____, 115 S. Ct. 1483, 1487 (1995), quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *English*, 496 U.S. at 79.

Congress may also provide expressly for preemption of state laws. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). Where Congress expressly provides for preemption of state laws, it is usually inappropriate to find implied preemption. *Cipollone*, 505 U.S. at 517; *Freightliner*, 115 S. Ct. at 1488. As the Court held in *Cipollone:* "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517.

Where a "statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transportation*, 507 U.S. at ____, 113 S. Ct. at 1737. However, where the meaning of an express preemption provision is

unclear or in doubt, there are six bedrock principles of statutory construction that the Courts must apply in ascertaining Congressional intent to displace state law.

First, under the "*Chevron* doctrine" enunciated by this Court, when an agency is entrusted with the responsibility to administer legislation, its interpretation of the meaning of that legislation is entitled to substantial deference by the Courts. *E.g.*, *Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*, _____ U.S. _____, 115 S. Ct. 2407, 2416 & 2418 (1995); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984); *Bowels v. Seminole Rock & Sand Co.*, 325 U.S. 410, 413-14 (1945). This doctrine was recently and firmly emphasized by this Court in the *Sweet Home* case where the Court deferred to the interpretation of a statute by an agency which had been "delegated broad administrative and interpretive power." *Sweet Home*, 115 S. Ct. at 2418.

Second, as a matter of comity dictated by principles of federalism, there is a strong presumption against preemption if it would mean superseding a state's historic police powers, which include the regulation of health and safety matters. *See, e.g.*, *Hillsborough County, Fla. v. Automated Medical Labs, Inc.*, 471 U.S. 707, 718 (1985); *Rice*, 331 U.S. at 230. Given this "strong presumption," preemption enactments are to be read "fairly but . . . narrowly" in relation to state laws governing health and safety. *E.g.*, *Cipollone*, 505 U.S. at 523.

Third, there is an even more compelling presumption that Congress would not, in the exercise of its plenary powers, "remove all means of judicial recourse for persons injured" by preempting traditional damage remedies available to injured parties under state law without affording a substitute damage remedy under federal law.[1] *E.g.*, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 250-51 (1984); *United Construction Workers v.*

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[1] Although this presumption against preemption is rooted in notions of federalism and the basic notions of fairness inherent in the statutory construction process, the presumption serves federal interests in a very practical way. Where a federal agency does not comply with its own regulations and

Laburnum Construction Corp., 347 U.S. 656, 663-64 (1954). As the Court opined in *Silkwood*, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood*, 464 U.S. at 251.

Fourth, evidence of a preemptive purpose may be derived from "the text and structure" of the legislation at issue. *See CSX Transportation, Inc.*, 507 U.S. at _____, 113 S. Ct. at 1737; *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983). *See also Sweet Home*, 115 S. Ct. at 2418 (interpretation based on "text and structure").

Fifth, in construing preemption statutes, the courts are obliged to follow the general principle of statutory construction which presumes that there is no surplusage in the language employed by Congress and therefore requires that all of the language of the legislative enactment be given effect. *See Sweet Home*, 115 S. Ct. at 2413; *Ratzlaf v. United States*, _____ U.S. _____, 114 S. Ct. 655, 659 (1994); *Macky v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 837 (1988).

Finally, legislative history plays an important role in ascertaining whether and to what extent Congress intended to preempt state law. *ACF Industries*, 114 S. Ct. at 851-52; *Silkwood*, 464 U.S. at 256. The Court's decision in *Silkwood* provides a good example of the application of this principle. There, the plaintiff sought to recover damages for injuries caused by a plutonium release at a nuclear facility regulated by the Nuclear Regulatory Commission. Even though the Court recognized

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injury results, the injured party may bring a federal tort claim against the United States under the Federal Tort Claims Act, 28 U.S.C. §2671 *et seq. See Berkovitz v. United States*, 486 U.S. 531 (1988). To the extent that a right to relief against a private party is available under state or federal law for such injuries, the incentives to initiate action against the United States are diminished proportionately. Thus, a rule that presumes that Congress would not preempt traditional damage remedies available to injured parties under state law without affording a substitute damage remedy under federal law is one which serves to reduce the potential for litigation against the United States under the Federal Tort Claims Act.

that the federal government occupied the entire field of nuclear safety regulation, it held that there was no Congressional intent to preclude damage awards under state law to persons injured in nuclear accidents because of the legislative history underlying nuclear regulation. As the Court said:

> No doubt there is tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a State may nevertheless award damages based on its own law of liability. But as we understand what was done over the years in the legislation concerning nuclear energy, Congress intended to stand by both concepts and to tolerate whatever tension there was between them. We can do no less.

Silkwood, 464 U.S. at 256.

It is with these important and guiding principles in mind that we now turn to examination of the specific issue presented here—whether plaintiffs' damage claims arising from the use of dangerous medical devices are preempted by federal law.

B. Application of General Preemption Principles Requires the Conclusion That State Laws of General Applicability, Including the Common Law and Most Products Liability Laws, Are Not Preempted by Federal Law Governing Medical Devices

In 1976 Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. *See* 21 *U.S.C.* §360a, *et seq.* The MDA contains an express preemption provision. It states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any

> requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 *U.S.C.* §360k(a).

The statute is unambiguous. By tying preemption to the presence of both a state requirement **"with respect to a device"** and an MDA requirement **"applicable to the"** device, it appears clear that preemption may not arise simply as the result of the existence of general legal requirements to which a device may be subject, but only as the result of laws and regulations that are specifically targeted at medical devices. This is consistent with prior Congressional enactments which have often drawn a distinction between preemption of specially targeted laws and preemption of generally applicable, background legal norms not directed at specific conduct in particular. *See, e.g., Cipollone*, 505 U.S. at 528-29 (no preemption because liability is predicated "on a more general obligation—the duty not to deceive"); *New York Telephone Co. v. New York State Department of Labor*, 440 U.S. 519, 550 (1979) (Congressional preemption of state power to "enforce . . . general laws is more difficult to infer than an intent to pre-empt laws directed specifically at concerted activity"); *United States Steelworkers of America v. Rawson*, 495 U.S. 362, 371 (1990) (the Court distinguished for purposes of labor law preemption between duties imposed on labor union by a collective bargaining agreement and generally applicable obligations such as "the duty of reasonable care owed to every person in society"); *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 107 (1992) (the Court held that the Federal Occupational Safety and Health Act of 1970 preempts only state law that "constitutes, in a direct, clear and substantial way, regulation of worker health and safety" and does not preempt "state laws of general applicability (such as laws regarding traffic safety or fire safety)"

despite their demonstrable effect on occupational safety).

However, in view of the conflicts that have developed in the Courts of Appeal in interpreting Section 360k it is certainly plausible to suggest that the reach of the statute is ambiguous. Given this, one must apply the six bedrock principles of pre-emption analysis outlined above to determine the extent to which Section 360k was intended to eliminate the availability of damage remedies under state law for injuries caused by medical devices.

Unquestionably, state tort law relates to matters of health and safety. *See* W. Prosser, *Handbook of the Law of Torts*, §5 at 23 (4th ed. 1971); Prentis and Roszkowski, *"Tort Reform" and the Liability "Revolution": Defending Strict Liability in Tort for Defective Products*, 27 *Gonz.L.Rev.* 251 (1992). In addition, there is no private right of action to recover damages or other relief under the MDA. *See, e.g., Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995); *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33 (M.D. Pa.), *aff'd without opinion*, 902 F.2d 1558 (3d Cir. 1989). Given the strong presumption against preemption of state laws relating to health and safety and the extreme admonition against adopting rules of preemption that would leave injured victims without a remedy, the preemption provision of the MDA should be given the narrowest reasonable construction in relation to state tort laws.

Plainly, a fair but narrow reading of Section 360k is that state law will not be preempted unless there is both a state requirement that specifically applies "with respect to a device" (as distinguished from a law of general application) and a federal requirement relating to "the" device and having the same subject matter as the state requirement, and then only to the extent that the state law imposes requirements which are "different from or in addition to" the specific federal requirement.

This is precisely the construction adopted by the FDA in regulations which it promulgated in 1978. These regulations,

intended to implement the provisions of Section 521, 21 *U.S.C.* §360k, specifically provide:

> State or local requirements are preempted only when the Food and Drug Administration has established **specific counterpart regulations** or there are other **specific requirements** applicable to a **particular** device under the act, thereby making any existing divergent State or local requirements **applicable to the device** different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> **(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.**
>
> **(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.**

21 *C.F.R.* §808.1(d)(1) & (2) (emphasis supplied).

Because most state tort law and products liability rules are laws of "general applicability" not specifically directed towards the regulation of medical devices, application of the syllogism contained in this regulation will not ordinarily permit

preemption of state laws governing liability for damages caused by injurious medical devices.

Since 1984, the FDA has consistently taken this position. For example:

> [I]n an Advisory Opinion issued under 21 *C.F.R.* §808.1, the Office of the Chief Counsel for the FDA stated:
>
> > Under section 521(a) [21 U.S.C. §360k] of the act, the act preempts only State and local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1435 (C.D. Cal. 1994) (emphasis in original).

In 1988 the FDA reiterated this position in a letter from Joseph M. Sheehan, Chief of its Regulations Staff, which stated:

> As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that

section 521 does not preempt general product liability requirements.[2]

And most recently, the FDA filed an Amicus Brief in *Talbot v. C.R. Bard, Inc.*, reasserting its position that plaintiffs may pursue damage remedies for injuries caused by federally regulated medical devices. *See Talbot v. C.R. Bard, Inc.*, 63 F.3d 25, 30 (1st Cir. 1995), *cert. pet. filed* (Feb. 16, 1996). *See also Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 247 n.8 (E.D. Pa. 1990) ("It is not the intent of FDA to influence the civil tort liability of the manufacturer").

Because the FDA is the agency charged with responsibility for administering the MDA, its views are entitled to substantial deference by the courts. *See* p. 5, *supra*. Indeed, judicial deference to the FDA's interpretation of the preemption provisions of the MDA should be particularly strong in light of the fact that Congress expressly made the FDA the arbiter of preemption by specifically authorizing it to allow exemptions from federal preemption in Section 521(b) of the statute, 21 *U.S.C.* §360k(b). *See Sweet Home*, 115 S. Ct. at 2418 (requiring substantial deference to regulatory interpretation of statutory language where agency given "broad administrative and interpretive power").

A narrow construction which holds that Section 360k should not preempt state laws of general applicability, including state tort law, is supported by the principle of statutory construction that eschews statutory surplusage and requires that every portion of a statute be accorded effect. Section 360k does *not* provide that "no state may establish or continue in effect any requirement which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." If it had done so, it would be clear that all state law "requirements" were encompassed within the ken of the statute. Rather, Congress

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[2] A copy of this letter is included in the Appendix to the Cross-Petitioners' Brief at p. 14a.

chose statutory language that prohibits states from establishing such requirements only "with respect to a device intended for human use." In order to avoid a statutory construction that renders this language surplusage and in order to give independent semantic significance to these words, it is necessary to construe the language as limiting preemption of state law requirements to those which are specifically targeted at medical devices intended for human use rather than those applying broadly to all state law requirements, as would be the case if the limiting statutory language were not present.

The FDA's narrow interpretation of Section 360k(a) is also supported by reference to the "text and structure" of the MDA as a whole. Specifically, 21 *U.S.C.* §360h allows the FDA to provide for "repair, replacement or refund" in situations where the agency determines that a device "presents an unreasonable risk" or "was not properly designed or manufactured" due to the failure of a "manufacturer, importer, distributor, or retailer of the device." *See* 21 *U.S.C.* §360h. Subparagraph (d) of that section provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Therefore, the statute specifically contemplates state law liability and damages notwithstanding the preemption provisions of Section 360k. *See Michael v. Shiley*, 46 F.3d 1316, 1326 (3d Cir.), *cert. denied*, _____ U.S. _____, 116 S. Ct. 67 (1995); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 & 1344 (11th Cir. 1995) ("savings clause [Section 360h] almost certainly prohibits a holding that the MDA preempts *all* state law liability"), *cert. granted*, _____ U.S. _____, 116 S. Ct. 806 (1996); *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994). This

buttresses the agency's narrow interpretation of Section 360k(a) which excludes product liability laws and remedies of general application from the scope of MDA preemption.

Finally, the legislative history convincingly supports the FDA's narrow interpretation of MDA preemption—that state laws of general applicability such as the common law and most product liability statutes, are not preempted by Section 360k(a). The Medical Device Amendments were passed in response to rapid technological changes in the medical device field and the perceived inadequacy of existing law to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." *S.Rep.No.* 33, 94th Cong., 2d Sess. 5, *reprinted in* 1976 *U.S. Code Cong. & Admin. News* 1070, 1075. The goal of the legislation was to "modify the underlying law in ways that will result in greater protection of the public health." *H.R. Rep.* No. 808, 101st Cong. 2d Sess. 13 (1990). As the sponsor of the bill stated, when introducing it on the Senate floor:

> The purpose of this legislation is to protect the health and safety of the American people . . . the legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for device malfunctions.

121 *Cong. Rec.* S. 6140 (April 17, 1975).

There is no question that products liability principles serve to promote public health and safety by establishing standards of conduct and providing a remedy for violation of those standards. *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 760 (S.D.N.Y. 1994); *Graham v. Wyeth Labs*, 666 F. Supp. 1483, 1493 (D. Kan. 1987); *MacGillivray v. Lederle Laboratories*, 667 F. Supp. 743, 745 (D.N.M. 1987); W. Prosser, *Handbook of the Law of Torts* §5 at 23 (4th ed. 1971). Therefore, eliminating tort liability for dangerous medical devices decreases the quantum of protection available to the public, denies the "benefit of the doubt" to the consumer and is thus incompatible with the

fundamental purpose of the legislation to provide greater protection of the public health. Thus, an interpretation of Section 360k which preserves, to the extent possible, the availability of traditional common law remedies is consistent with the central animating objective of the legislation.

Second, the MDA was enacted against the background of substantial litigation concerning injuries caused by medical devices, particularly the Dalkon Shield IUD.[3] In this context, a proposal to immunize medical device manufacturers from liability would, no doubt, have generated considerable controversy. Experience with similar measures suggests that if preemption were intended by Congress there would have been an extensive discussion of alternatives short of total immunity such as capping liability or perhaps eliminating strict liability and requiring a showing of negligence. Yet, tort reform is never discussed in the legislation or in its legislative history.

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[3]For example, the House Report on the 1976 Medical Device Amendments states:

> An example of a legitimate medical device which was marketed without adequate premarket testing is the Dalkon Shield. . . . By mid-1975, the Shield had been linked to sixteen deaths and twenty-five miscarriages. Presently, more than 500 lawsuits seeking compensatory and punitive damages totalling more that $400 million are pending against the manufacturer of the Shield. . . .

H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976). The Dalkon Shield was cited numerous times during the debates on the MDA in both the House and Senate. 122 Cong. Rec. H1719-1731 (daily ed. March 9, 1976); 121 *Cong. Rec.* S6139-6162 (daily ed. April 17, 1975). Liability claims eventually led the manufacturer of the Shield, A.H. Robins, to declare bankruptcy, at which time more than 300,000 women filed claims against the company for Dalkon Shield-related injuries and illness. *See* Richard B. Sobol, *Bending the Law: The Story of the Dalkon Shield Bankruptcy* (1991); Stephanie Goldberg, *Manufacturers Take Cover*, 72 A.B.A.J. 52 (July 1986). From 1974 to 1986, half of all product liability lawsuits filed in federal courts in the United States against pharmaceutical manufacturers were filed against A.H. Robins with respect to injuries or death allegedly caused by the Dalkon Shield. *See* Terence Dungworth, *Product Liability and the Business Sector: Litigation Trends in Federal Courts*, 52 (1988) (study for the RAND Corporation).

The only section of legislative history discussing the logic behind the adoption of Section 360k's language is House Report No. 853. *See H.R. Rep.* No. 853, 94th Cong., 2nd Sess. This report focuses on the need for nationwide uniformity in medical device approval in light of the haphazard regulatory efforts which states were beginning to adopt in the absence of meaningful federal regulation of medical devices. The House Report indicates that the Congressional purpose behind Section 360k was merely to prevent the states from establishing administrative mechanisms for clearance of medical devices in the absence of federal approval. *See H.R. Rep.* No. 853, 94th Cong., 2d Sess. at 45-46 (1976). Nowhere in the report or in any of the legislative history does Congress mention the effect of the legislation on state tort actions much less manifest an intent to limit or preclude such actions. *See Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459-60 (9th Cir. 1995); *Bravman*, 842 F. Supp. at 755 n.4, citing 121 *Cong. Rec.* 10, 687-710 (1975); *S.Rep.* No. 33, 94th Cong., 2d Sess. 3, *reprinted in* 1976 *U.S. Code Cong. & Admin. News* 1070-103; *House Conf. Rep.* No. 1090, 94th Cong., 2d Sess. 3, *reprinted in* 1976 *U.S. Code Cong., & Admin. News* 1103-18; *House Rep.* No. 853, 94th Cong., 2d Sess. (1976). *See also Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1300 (D. Minn. 1988). As a matter of logic, it is difficult to conclude that Congress intended to eliminate or seriously restrict tort liability resulting from dangerous medical devices without such a dramatic consequence even being mentioned in the legislative history, particularly in a piece of legislation which was specifically enacted against a background of extensive tort litigation concerning medical devices and which was specifically designed to add to the protections available to consumers of medical devices. *See, e.g., Kennedy*, 67 F.3d at 1459-60; *Callan*, 709 F. Supp. at 667; *Kociemba*, 680 F. Supp. at 1300; *Haudrich v. Howmedica, Inc.*, 267 Ill.App.3d 630, 204 Ill. Dec. 744, 642 N.E.2d 206, 214 (1994), *aff'd*, 1996 W.L. 19012 (Ill., Jan. 18, 1996).

Accordingly, application of the rules of preemption analysis frequently articulated by this Court amply warrants the conclusion that the MDA cannot and should not be construed as preempting legal requirements of general applicability such as the common law, tort law, and product liability principles. This is not to say that there will never be preemption of state tort law as applied to medical devices. A device-specific federal labeling regulation may, for example, preempt a state law failure-to-warn claim under the principle of implied actual conflict preemption discussed above. *See* p. 4, *supra*; *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989). However, it is to say that in enacting Section 360k, Congress did not manifest an intent to preempt the operation of general state law requirements as applied to medical devices. Tort damage remedies should not be eviscerated simply because the offending agent is a medical device as opposed to some other type of harmful product.

C. Claims Arising From Conduct That Violates the Federal Medical Device Law Are Not Preempted

Preemption of state law under Section 360k is sharply limited by the language that expressly confines preemption to the establishment or enforcement of state law "requirements" which are "different from or in addition to" federal requirements established pursuant to the MDA. *See* 21 *U.S.C.* §360k(a). The only sensible construction of this language is that the MDA does not preempt state law damage claims which arise from conduct in violation of federal requirements imposed under the MDA itself.

Such a construction is supported by the plain meaning of the statute—to the extent that state law allows recovery for conduct which violates federal law, it does not impose "different" or "additional" requirements, but rather serves as a means to underscore and enforce the federal requirements. *See Michael v. Shiley*, 46 F.3d at 1328; *Sylvester v. Mentor Corp.*, 663 So. 2d 176, 180-181 (La.App. 3d Cir. 1995), *writ denied*, 95-2936, _____ So. 2d _____ (La., Feb. 16, 1996).

This interpretation is also supported by the principle of statutory construction which requires that all the language of a legislative enactment be given effect. *See, e.g., Sweet Home*, 115 S. Ct. at 2413; *Ratzlaf*, 114 S. Ct. at 659; *Macky*, 486 U.S. at 837. If preemption were triggered merely by the existence of a federal requirement having the same subject matter as a state requirement, then the language limiting preemption to state requirements which are "different from or in addition to" federal requirements would be meaningless surplusage, unless the imposition of a damage remedy under state law could be considered a "requirement" under the statute which is "different from or in addition to" the remedies provided by federal law. However, this Court has consistently held that the availability of a damage remedy under state law, as distinguished from the substantive obligation for which the law may afford that relief, is not a "requirement for purposes of preemption." *Cipollone*, 505 U.S. at 526; *American Airlines, Inc. v. Wolens*, _____ U.S. _____, 115 S. Ct. 817, 824 (1995). Therefore, in order to give effect to the limitation of preemption contained in the "different from or in addition to" language of the statute and the teachings of this Court that the provision of a damage remedy, by itself, does not impose a "requirement," it is essential to construe the statute as permitting the imposition of duties under state law to the extent that they are not different from or in addition to those imposed by federal law.

Moreover, an interpretation of the statute which allows damage remedies under state law for conduct in violation of a federal requirement carries into effect the express preservation of state law damage remedies provided for by Congress in Section 360h of the statute. *See* 21 *U.S.C.* §360h(d). Indeed, a contrary construction—that state law remedies are "requirements" that are preempted by the availability of FDA enforcement actions—would be directly contrary to the provisions of Section 360h(d), which expressly preserve "liability under federal or state law" for "damages." *See* 21 *U.S.C.* §360h(d); *see*

also Michael v. Shiley, 46 F.3d at 1326 (Congress "g[a]ve indications in 21 *U.S.C.* §360h that at least some common law remedies would remain in conjunction with FDA regulation"). And, to the extent that there is ambiguity on this point, the presumption against preemption of state law remedies requires resolution of that ambiguity in favor of a rule which preserves the existence of state law damage remedies. *See Cipollone*, 505 U.S. at 523; *Hillsborough*, 471 U.S. at 718; *Silkwood*, 464 U.S. at 250-51; *United Construction Workers*, 347 U.S. at 663-64.

An interpretation of the statute which preserves the availability of state law damage remedies to the extent that a manufacturer's conduct is in violation of federal law is also supported by the legislative history of the MDA. As we demonstrated earlier, Congress' sole purpose in enacting the preemption provisions of the MDA was to eliminate haphazard regulation of medical devices by the states and not to foreclose private parties from obtaining a remedy for injuries caused by unsafe medical devices. *See* Part III(B), *supra*. An interpretation of the MDA which permits plaintiffs to recover under state law for conduct that violates the MDA serves this legislative purpose.

Moreover, the FDA's own regulations, which the Court is obliged to apply under the *Chevron* doctrine, explicitly support the conclusion that the MDA does not preempt state law to the extent that it allows recovery for conduct that violates the federal law. Specifically, those regulations state:

> Section [360k(a)] does not preempt State or local requirements that are equal to, or substantially identical to, the requirements imposed by or under [federal medical device law].

21 *C.F.R.* §808.1(d)(2). *See Sweet Home*, 115 S. Ct. at 2416 & 2418; *Chevron*, 467 U.S. at 844; *Bowels*, 325 U.S. at 413-414.

Finally, a rule that permits state law claims to the extent that they are predicated on violations of federal medical device law does not transgress the established principle that there is no implied private right of action under the Food, Drug and Cosmetic Act for two discrete reasons.

First, when liability is imposed for conduct that violates the provisions of the Food, Drug and Cosmetic Act, it is imposed under principles of state law which employ statutes and regulations as applicable standards of care and allow damages when the state law prerequisites to damages such as proximate cause and injury are also established. *See, e.g., Stanton-By-Brooks v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 563-65 (3d Cir. 1983); *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 460-61 (4th Cir. 1960); *Toole v. Richardson-Merrell, Inc.*, 251 Cal.App. 2d 689, 703-04, 60 Cal.Rptr. 398 (lst Dist. 1967). Federal law has long recognized the appropriateness of this common law practice. *Id. Cf. Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986) (holding that a state law claim based on violation of the Food, Drug and Cosmetic Act was not a claim "arising under" federal law within the meaning of 28 *U.S.C.* §1331, but nowhere suggesting that a cause of action under state law did not exist).

Second, federal courts are less likely to recognize private rights of action under federal statutes where state law remedies are available. *See Cort v. Ash*, 422 U.S. 66, 78 (1975) (noting that the availability of an implied right of action under a federal statute turns, in part, on whether "the cause of action [is] one traditionally relegated to state law, in an area basically the concern of the States, so that it would be inappropriate to infer a cause of action based solely on federal law"). Thus, the failure of federal law to recognize an implied right of action under the Food, Drug and Cosmetic Act **strengthens** the argument that plaintiffs may seek relief under state law at least to the extent that state law does not impose requirements that are "different from or in addition to" the federal requirements.

In light of these considerations, the better-reasoned decisions in the Courts of Appeal have held that state law claims arising from conduct that violates the Federal Medical Device Law are not preempted. *E.g., National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 993 (8th Cir. 1994) ("when a statute only preempts state requirements that are different

from or in addition to those imposed by federal law [like the MDA], plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements"); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1281-82 (7th Cir. 1995), *cert. pet. filed* (Feb. 20, 1996) ("In the absence of a more explicit legislative or regulatory direction, we hesitate to say, therefore, that an adulteration claim based on a product's failure to meet PMA standards—standards that have been explicitly set forth by the FDA—does not survive MDA preemption. Such a claim seeks merely to enforce the federal standard, not to add requirements 'different from, or in addition to,' it"); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) (preemption under the MDA is "limited to efforts by states to impose sanctions for compliance with federal regulations"); *Sylvester*, 663 So. 2d at 180-181 (we find no preemption of state law award of damages for violation of FDA's own requirements for a particular device); *Reiter v. Zimmer*, 897 F. Supp. 154, 160-162 (S.D.N.Y. 1995) ("a state action does not impose an 'additional requirement' simply because it might give rise to an obligation to pay money damages that might not arise under federal law . . . [plaintiffs'] negligent manufacturing claim, limited in scope to questions of compliance with existing FDA regulations and questions of proximate causation and damages, is an appropriate mechanism in support of federal law, and is therefore not preempted"); *Reiter v. Zimmer*, 830 F. Supp. 199, 204 (S.D.N.Y. 1993) ("refusing to extend preemptive reach of MDA to a negligence claim against a manufacturer that allegedly violated FDA requirements"); *Ministry of Health v. Shiley*, 858 F. Supp. at 1439 ("the MDA would *not* preempt claims that the manufacturer *negligently failed to comply with the FDA's regulations*, since a finding of wrongdoing would merely impose those regulations already imposed by the statute, and would not be 'different from or in addition to' those imposed by the MDA"); *Evraets v. Intermedics Intraocular, Inc.*, 29 Cal.App. 4th 779, 791, 34 Cal.Rptr. 2d 852, 859 (1994) ("State actions which echo or attempt to enforce

federal standards are not preempted"); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, _____ U.S. _____,115 S. Ct. 2614 (1995) ("Martello did not claim the AOSEPT he used did not comply with federal regulations").

Those appellate decisions which have extended preemption to claims arising from conduct in violation of the provisions of the MDA, like the Eleventh Circuit in the present matter, have done so primarily because of philosophical reasons or concerns with the difficulties in implementing such a rule. *See Lohr*, 56 F.3d at 1343 and *Talbot*, 63 F.3d at 29. Such philosophical or practical considerations are, however, immaterial. Under this Court's preemption jurisprudence, these considerations attendant to the question of preemption are a matter of legislative and not judicial concern. Therefore, in interpreting an express preemption provision, the sole question properly before a court is the extent to which the language used by Congress delimits the scope of preemption. By expressly providing that preemption of state requirements with respect to medical devices is limited to the establishment or enforcement of state law "requirements" which are "different from or in addition to" federal requirements established under the MDA, Congress plainly crafted such a limitation on preemption.

IV. CONCLUSION

For the foregoing reasons, Amicus Curiae respectfully submits that to the extent that the Opinion and Order of the United States Court of Appeals for the Eleventh Circuit found in favor of Cross-Petitioners, Lora Lohr and Michael Lohr, it should be affirmed and that to the extent that it ruled against them, the Opinion and Order should be reversed.

Respectfully submitted,

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